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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,186	10/22/2003	John Girdner Atwood	07759-019004	6805
35411	7590	03/24/2005	EXAMINER	
KILYK & BOWERSOX, P.L.L.C. 3603 CHAIN BRIDGE ROAD SUITE E FAIRFAX, VA 22030			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,186	Applicant(s) ATWOOD ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2004 and 09 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 219-257 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 219-257 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 9/18/2004 has been considered and made of record. Note the information disclosure statement filed 8/31/2004 has not been made of record because a Form PTO-1449 was not filed with the IDS.

Compact Disc Submission

2. The description portion of this application contains a computer program listing consisting of more than three hundred (300) lines. In accordance with 37 CFR 1.96(c), a computer program listing of more than three hundred lines must be submitted as a computer program listing appendix on compact disc conforming to the standards set forth in 37 CFR 1.96(c)(2) and must be appropriately referenced in the specification (see 37 CFR 1.77(b)(4)). Accordingly, applicant is required to cancel the computer program listing appearing in the specification on pages 174, line 12 to page 231LLL, file a computer program listing appendix on compact disc in compliance with 37 CFR 1.96(c) and insert an appropriate reference to the newly added computer program listing appendix on compact disc at the beginning of the specification.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Applicants are requested to carefully check the instant specification to ensure that the "Brief Description of the Drawings" corresponds to the figure numbering employed on the drawing filed 10/22/2003.

Applicants are also requested to carefully check the instant specification with respect to references to "microfiche" appendices. Note this application was not filed with any microfiche appendices.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 219-257 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 219 appears to invoke 35 USC 112, sixth paragraph, when reciting "means for determining the temperature of the block". However, it is not clear from the instant jumbo specification what structures and/or equivalents thereof are intended to be encompassed by this means plus function language. It appears that a temperature sensor in thermal contact with the block would be an equivalent structure. Also see claim 235 which render the language even more indefinite. This claim recites that the "means for determining" "comprises means for determining". Also use of the language "is capable of" with respect to the computing apparatus is indefinite. It is not clear from this claim language if the computing apparatus actually performs the stated determination or would merely be capable of performing the stated

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determination. Note any microprocessor that can be programmed would be capable of performing the stated determination if programmed to do so.

Claim 225 appears to invoke 35 USC 112, sixth paragraph, when reciting “means for determining an actual heating power” that includes a plurality of sub-means. However, it is not clear from the instant jumbo specification what structures and/or equivalents thereof would be encompassed by this claim language. The instant claim language would imply that the means would be merely a computer algorithm since it has been recited as being part of the computing apparatus. However, review of the instant specification reviews that the means would require temperature sensors for determining the temperature of coolant and the ambient environment. As a result, it is not entirely clear what structures are intended to be covered by this means plus function claim language.

Claims 227-238 are indefinite for the same reasons as set forth with respect to claim 225. It is not clear if the recited means are merely computer code or algorithms or include additional structures such as sensors and mechanical control devices in response to the computing apparatus.

In claim 239 use of the language “is capable of” with respect to the computing apparatus is indefinite. It is not clear from this claim language if the computing apparatus actually performs the stated determination or would merely be capable of performing the stated determination. Note any microprocessor that can be programmed would be capable of performing the stated determination if programmed to do so.

Claims 245-257 are indefinite for the same reasons as set forth with respect to claim 239 in view of the language “is capable of”.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 219-221 and 239-241 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al.(WO 89/09437).

With respect to claim 219, the reference of Dean et al. discloses an apparatus (10) that includes a heating and cooling system (12,14); a sample block (16) including at least one well (17). The sample block is capable of thermal contact with the heating and cooling system (12,14). The apparatus includes means for determining the temperature of the block (See pages 6-7 and element (22)). The apparatus includes a computing apparatus (See sub-housing (18) and page 5, line 24, to page 6, line 3) to control the heating and cooling system. With respect to the recited claim language that the “computing apparatus is capable of determining the temperature of a liquid sample mixture” based on the recited algorithm, the reference of Dean et al. discloses that “the microprocessor being programmed to anticipate the time lag between the support temperature and the reaction temperature if only the support is sensed” (See page 4) and the reference discloses the use of an algorithm for predicting the sample temperature based on the block temperature (See page 15). Note the instant claim language of claim 219 is not considered to be limited to the specific algorithm listed in the claim since the instant claim language merely

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recites that computing apparatus “is capable of determining”. The computing apparatus of the reference of Dean et al. is structurally the same because the computing apparatus of Dean et al. “is capable” of being programmed with the algorithm recited in the claim. Note statements of intend use carry no patentable weight in apparatus-type claims.

With respect to claim 220, the limitation of claim 220 is not considered a positively recited claim limitation of the structure since the algorithm has not been positively recited as part of the claimed device. See the comments above with respect to claim 219.

With respect to the input device of claim 221, the reference of Dean et al. discloses the use of a keyboard as an input device (See pages 7 and 11).

Claims 239-241 are anticipated by the reference of Dean et al. for the same reasons set forth with respect to claims 219-221 above.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 226-228 and 230-232 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al.(WO 89/09437).

The reference of Dean et al. has been discussed above.

With respect to claims 222 and 242, while the reference of Dean et al. discloses a block (16) with wells (17), the reference is silent as to the specific dimensions of the wells.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the size of the wells based merely on the desired size sample tubes intended to be used in the temperature control system.

With respect to the limitations of claims 231-238 and 251-257, while the reference of Dean et al. discloses that the device includes an input device (keyboard) and that the device is required to operate at a specific temperature/time profile, the reference is silent as to the specific

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various control parameters with respect to the temperature control in terms of overshoot, undershoot, tube size, sample volume, etc.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum control parameters to perform a desired PCR reaction based on considerations such as the specifics of the reaction to be performed in terms of the sample source and the reagents employed while maintaining the efficiency of the reaction system.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 219-257 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-10, 26-28, 31, 42, 44, 45, 53, 54, 59, 97, 98 and 117 of U.S. Patent No. 5,475,610. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either

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anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 219-257 are generic to all that is recited in claims 1-3, 7-10, 26-28, 31, 42, 44, 45, 53, 54, 59, 97, 98 and 117 of U.S. Patent No. 5,475,610. That is, claims 1-3, 7-10, 26-28, 31, 42, 44, 45, 53, 54, 59, 97, 98 and 117 of U.S. Patent No. 5,475,610 fall entirely within the scope of claims 219-257 or, in other words, claims 219-257 are anticipated by claims 1-3, 7-10, 26-28, 31, 42, 44, 45, 53, 54, 59, 97, 98 and 117 of U.S. Patent No. 5,475,610.

14. Claims 219, 223-225, 239 and 243-245 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 6,703,236. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 219, 223-225, 239 and 243-245 are generic to all that is recited in claims 7-9 of U.S. Patent No. 6,703,236. That is, claims 7-9 of U.S. Patent No. 6,703,236 fall entirely within the scope of claims 219, 223-225, 239 and 243-245

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or, in other words, claims 219, 223-225, 239 and 243-245 are anticipated by claims 7-9 of U.S.


Patent No. 6,703,236.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB